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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,910	02/01/2006	6175752	518852800100	2596

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EXAMINER

Erik Kielin

ART UNIT

PAPER NUMBER

3992

IFW

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/007910

PATENT NO. 6,175,752

ART UNI 3992

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/007,910	6175752	
	Examiner	Art Unit	
	Erik Kielin	3992	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 01 February 2006 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☒ PTO-892, b) ☐ PTO-1449, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the date of service of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
b) ☐ by credit to Deposit Account No. _____, or
c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

Erik Kielin
Primary Examiner
Art Unit: 3992

cc:Requester (if third party requester)



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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/007,910.

PATENT NO. 6175752.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Application/Control Number: 90/007,910

Page 2

Art Unit: 3992

DECISION ON REQUEST FOR REEXAMINATION

A substantial new question of patentability affecting claims 1-12, 14-35, 38-40, 42-45, 49-51, 53, 54, 58-65, 74-86, 88-90, and 92-94 of Patent Number US 6,175,752 to James Say et al. (the '752 patent, hereafter) is raised by the request for *ex parte* reexamination.

The References

- (1) EP Patent Application No. 83106571.9 to Shichiri et al., entitled "Portable Artificial Pancreas," filed July 5, 1983, published January 18, 1984 as EP publication no. 0098592 A2 (hereinafter "Shichiri I")
- (2) Shichiri et al., "Telemetry Glucose Monitoring Device With Needle-Type Glucose Sensor: A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," *Diabetes Care*, Vol. 9, No. 3, pp. 298-301, May-June 1986 (hereinafter "Shichiri II")
- (3) Ko et al., (Ed.), "Implantable Sensors for Closed-Loop Prosthetic Systems," Mount Kisco, NY: Futura Publishing Company, Inc., 1985, Chapter 15, entitled "Needle-type Glucose Sensor for Wearable Artificial Endocrine Pancreas," pp. 197-210 (hereinafter, "Shichiri III")
- (4) U.S. Patent No. 5,569,186 to Lord et al., entitled "Closed Loop Infusion Pump System With Removable Glucose Sensor," filed April 25, 1994, issued October 29, 1996 (hereinafter "Lord I")
- (5) U.S. Patent No. 4,494,950 to Fischell, entitled "Plural Module Medication Delivery System," filed January 19, 1982 and issued January 22, 1985 (hereinafter "Fischell")
- (6) U.S. Patent No. 5,390,671 to Lord et al., entitled "Transcutaneous Sensor Insertion Set," filed March 15, 1994, issued February 21, 1995 (hereinafter "Lord II")
- (7) PCT Application No. PCTIUS96/02006 to Cheney et al., entitled "Transcutaneous Sensor Insertion Set," filed February 14, 1996, claiming priority to U.S. application no. 08/393,159, published on August 22, 1996 as WO 96/25089 (hereinafter "Cheney")
- (8) U.S. Patent No. 5,957,854 to Besson et al., entitled "Wireless Medical Diagnosis And Monitoring Equipment," filed December 5, 1997, claiming priority to PCT/EP94/02926, filed September 2, 1994 (now U.S. 5,862,803) (hereinafter "Besson")
- (9) U.S. Patent No. 6,219,574 to Cormier et al., entitled "Device And Method For Enhancing Transdermal Sampling," filed June 17, 1997, claiming priority to provisional application no. 60/019,990, filed June 18, 1996, issued on April 17, 2001 (hereinafter "Cormier")
- (10) U.S. Patent No. 4,703,756 to Gough et al., entitled "Complete Glucose Monitoring System With An Implantable Telemetered Sensor Module," filed May 6, 1986, issued November 3, 1987 (hereinafter "Gough")

Application/Control Number: 90/007,910

Page 3

Art Unit: 3992

- (11) Stuart J. Updike et al., "Principles of Long-term Fully Implanted Sensors With Emphasis On Radiotelemetric Monitoring of Blood Glucose From Inside a Subcutaneous Foreign Body Capsule (FBC)," *Biosensors in the Body: Continuous in vivo Monitoring*, Edited by David M. Fraser, Chapter 4, pp. 117-137, April 16, 1997, John Wiley & Sons Ltd, (hereinafter "Updike")
- (12) Mark C. Shults et al., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors," *IEEE Transactions On Biomedical Engineering*, Vol. 41, No. 10, pp. 937-942, October 1994, 1994 IEEE (hereinafter "Shults")
- (13) Brian D. McKean et al. "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," *IEEE Transactions On Biomedical Engineering*, Vol. 35, No. 7, July 1988 IEEE (hereinafter "McKean")
- (14) Jon C. Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," *Diabetes*, Vol. 39, December 1990 (hereinafter "Armour")
- (15) Michael Thompson et al., "In Vivo Probes: Problems and Perspectives," *Clinical Biochemistry*, Vol. 19, October 1986 (hereinafter "Thompson")
- (16) G. Velho et al., "Strategies for calibrating a subcutaneous glucose sensor," *Biomed. Biochim. Acta* 48 (presented at the International Workshop on Intracorporeal Glucose Sensors," September 27-30, 1988, Gohren-Lebbin, GDR) (hereinafter "Velho")
- (17) European Patent Application No. 90302932.0 to Skotheim et al., entitled "Electrochemical biosensor based on immobilized enzymes and redox polymers," filed on March 19, 1990, published as EP 0 390 390 A1 on October 3, 1990 (hereinafter "Skotheim")
- (18) U.S. Patent No. 4,538,616 to Rogoff entitled "Blood Sugar Level Sensing and Monitoring Transducer," filed on July 25, 1983, issued on September 3, 1985 (hereinafter "Rogoff")

Prosecution History

The examiner of the application (09/070,677, the '677 application, hereafter) that became the '752 patent provided no specific reasons for allowance. However, during the prosecution of the '677 application, some of the claims (including claim 1) was twice amended (1) to further limit the transmitter to an RF transmitter (Applicant's amendment filed 29 July 1999); (2) to further limit the electrochemical sensor to be transcutaneous (i.e. a portion extending out of the skin) (Applicant's amendment filed 20 March 2000). Accordingly, the amended features required to gain allowance of the '677 application claims are considered significant in determining the patentability of the '752 claims. With this in mind, prior art disclosing a sensor control unit (1) electrically connected to a *transcutaneous* electrochemical sensor and (2) having an RF transmitter may be considered to raise a substantial new question of patentability.

Application/Control Number: 90/007,910

Page 4

Art Unit: 3992

In addition, it is noted that '752 claim 32 does not require a transmitter of any kind and was never amended during the prosecution of the '677 application. Accordingly, prior art disclosing each of the features of claim 32 would raise a substantial new question of patentability.

Substantial New Question of Patentability

(1) The Request indicates that Requester believes claim 1 is anticipated by each of Shichiri I, Lord I, and Fischell. (See Request at pages 10 and 14-32.)

Before beginning, Examiner notes that Requester states "Shichiri II and Shichiri III have the same or very similar disclosures as Shichiri I (Request, p. 12, third paragraph). For the purposes of determining a substantial new question of patentability, then, Shichiri II and Shichiri III are taken to be cumulative references to Shichiri I, and only Shichiri I will be addressed because this reference provided the most detail of the three. (See also Request at pages 16-17.)

Shichiri I

Examiner incorporates by reference, the locations in Shichiri I, as cited in the Request, wherein the features of the above claim can be found. Of particular relevance, Shichiri I discloses the **transcutaneous sensor 13** connected to a sensor control unit **2** (Figs. 1-3) including an RF transmitter **11** (Fig. 2). Shichiri I provides a new teaching in terms of the combination of elements disclosed in a single reference not before the examiner of the '677 application. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Shichiri I raises a substantial new question of patentability as to claim 1.

Lord I

The substantial new question of patentability based on Lord I is based solely on patents and/or printed publications already cited/considered in an earlier concluded examination of the patent being reexamined. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a **case-by-case basis**.

Application/Control Number: 90/007,910

Page 5

Art Unit: 3992

In the present instance, there exists a SNQ based solely on Lord I. A discussion of the specifics now follows:

While Lord I was present before the examiner during the examination of the '677 application, the reference was not relied on to reject the claims. When a substantial new question of patentability is raised solely over previously cited art, the Court stated in the sole footnote, in *In re Robert T. Bass*, 314 F.3d 575, 576-77, 65 USPQ2d 1156, 1157 (Fed. Cir. 2002), in pertinent part,

“37 CFR 1.2 requires that all Office business be transacted in writing. Thus, the Office cannot presume that a prior art reference was previously relied upon or discussed in a prior Office proceeding if there is no basis in the written record to so conclude other than the examiner’s initials or a check mark on a PTO 1449 form, or equivalent, submitted with an information disclosure statement. Thus, any specific discussion of prior art must appear on the record of a prior related Office proceeding.”

Because no written consideration of Lord I exists in the record of the '677 application, Lord I cannot be excluded as a reference raising a substantial new question of patentability.

Examiner incorporates by reference, the locations in Lord I, as cited in the Request, wherein the features of the above claim can be found. Of particular relevance, Lord I discloses the **transcutaneous** glucose sensor **20** (Figs. 1-3) connected to a sensor control unit including an RF transmitter **26** (Fig. 1; col. 3, lines 58-67). There is a substantial likelihood that a reasonable examiner would consider the disclosure of the combination of features taught in this single reference important in deciding whether or not the claims are patentable. Accordingly, Lord I raises a substantial new question of patentability as to claim 1.

Fischell

Examiner incorporates by reference, the locations in Fischell, as cited in the Request, wherein the features of the above claim can be found. Of particular relevance, Fischell discloses the **transcutaneous** sensor **14b** (Figs. 1 and 4) connected to a sensor control unit **14a** (Fig. 4) including an RF transmitter **65** (Fig. 4; col. 6, lines 29-33 [note this citation is incorrectly cited in the Request as **col. 4**, lines 29-33]). Fischell provides a new teaching in terms of the combination of elements disclosed in a single reference not before the examiner of the '677 application. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Fischell raises a substantial new question of patentability as to claim 1.

(2) The Request indicates that Requester believes claims 1-12, 14-19, 30, 32-35, 38, and 89 are obvious over any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney. (See Request at pages 10-14.)

Application/Control Number: 90/007,910

Page 6

Art Unit: 3992

Examiner incorporates by reference, the locations in each of Shichiri I, II, III, Lord I, and Fischell, as cited in the Request, wherein the features of the above claims can be found. Each of the features has been discussed just above.

Each of Lord II and Cheney teaches a **transcutaneous**, thin-film electrochemical sensor for monitoring glucose that is more closely related to the thin-film electrochemical sensor disclosed in the '752 patent than in each of Shichiri I, II, III, Lord I, and Fischell. As a result, the contact pads of Lord II and Cheney more closely read on those contact pads disclosed --but not necessarily claimed-- in the '752 claims. As considered with each of the features taught in Shichiri I, II, III, Lord I, and Fischell, then, these combinations of references provide new teachings not before the examiner of the '677 application. There is a substantial likelihood that a reasonable examiner would consider these combined teachings important in deciding whether or not the claims are patentable. Accordingly, any of Shichiri I, Shichiri II, Shichiri III, Lord I, and Fischell in view of either of Lord II and Cheney each raises a substantial new question of patentability of claims 1-12, 14-19, 30, 32-35, 38, and 89.

(3) The Request indicates that Requester believes claims 20-25, 27, 28, 31, 39, 40, 42-45, 49-51, 53, 54, 58-64, 76-86, 88, 90, and 92-94 are obvious over Shichiri I in view of either of Lord II and Cheney. (See Request at pages 10-14.)

This issue merely omits Lord I and Fischell; therefore a substantial new question of patentability is raised for the same reasons as discussed in section enumerated "(2)" above.

(4) The Request indicates that Requester believes claims 26-29 and 31 are obvious over Fischell in view of either of Lord II and Cheney. (See Request at pages 10-14.)

This issue merely omits Lord I and Shichiri I; therefore a substantial new question of patentability is raised for the same reasons as discussed in section enumerated "(2)" above.

(5) The Request indicates that Requester believes claims 39, 40, 42-44, 49, 50, 76-82, 84, 85, 88, 90, and 92-94 are obvious over Lord I, in view of either of Lord II and Cheney. (See Request at pages 10-14.)

This issue merely omits Shichiri I and Fischell; therefore a substantial new question of patentability is raised for the same reasons as discussed in section enumerated "(2)" above.

Application/Control Number: 90/007,910

Page 7

Art Unit: 3992

(6) The Request indicates that Requester believes claims 9, 10, and 17-19 are obvious over any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney and further in view of Cormier. (See Request at pages 10-14.)

The combined teachings of any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney have been discussed in section enumerated “(2)” above.

Examiner incorporates by reference, the locations in Cormier, as cited in the Request, wherein the features of the above claims can be found.

Cormier teaches the sensor control unit is water resistant or water proof (Cormier, col. 9, lines 37-41) and contains a “button cell battery 32” (Cormier, col. 8, lines 52-54). Considered with the features disclosed in any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with Cormier raises a substantial new question of patentability as to claims 9, 10, and 17-19 of the ‘752 patent.

(7) The Request indicates that Requester believes claims 17-19 are obvious over any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney and further in view of Besson. (See Request at pages 10-14.)

The combined teachings of any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney have been discussed in section enumerated “(2)” above.

The Request alleges that Besson teaches a battery, but the Request points out that Besson teaches only an “energy supply unit 37” located in the electrode assembly. Moreover, Besson does not teach that “energy supply unit 37” is a battery. All energy-supplying devices are not batteries. Solar cells are energy supply units that are **not** batteries. Therefore, Requester errs in suggesting that Besson teaches this feature. Furthermore, there is a substantial likelihood that a reasonable examiner would **NOT** consider this combined teaching important in deciding whether or not claims 17-19 are patentable because the feature itself is not taught. Therefore, the Request **fails** to raise a substantial new question of patentability as to claims 17-19 over any of Shichiri I, Lord I, and Fischell in view of either of Lord II and Cheney and further in view of Besson.

(8) The Request indicates that Requester believes claims 29, 74, and 75 are obvious over either of Shichiri I (claims 29, 74, and 75) and Lord I (claims 74 and 75) in view of either of Lord II and Cheney and further in view of either Besson (claims 74 and 75) or Fischell (claim 74 only). (See Request at pages 10-14 and 86.)

Application/Control Number: 90/007,910

Page 8

Art Unit: 3992

The combined teachings of any of Shichiri I and Lord I in view of either of Lord II and Cheney have been discussed in section enumerated “(2)” above.

Besson teaches a temperature measuring device. However, there is no suggestion in any of the references, particularly Besson, that the temperature measurement device is used to correct data obtained from the sensor, as alleged by Requestor. Requestor errs in this statement. Furthermore there is a substantial likelihood that a reasonable examiner would **NOT** consider this combined teaching important in deciding whether or not claims 29, 74, and 75 are patentable because the feature itself is not taught. Accordingly, the Request **fails** to raise a substantial new question of patentability as to claims 29, 74, and 75 using Besson.

Similarly, Fischell teaches an internal sensor 16 which may be for temperature measurement but, like Besson, fails to provide a suggestion that the temperature measurement device is used to correct data obtained from the sensor, as alleged by Requestor. Requestor errs in this statement. Furthermore there is a substantial likelihood that a reasonable examiner would **NOT** consider this combined teaching important in deciding whether or not claim 74 is patentable because the feature itself is not taught. Accordingly, the Request **fails** to raise a substantial new question of patentability as to claim 74 using Fischell.

(9) The Request indicates that Requester believes claim 45 is obvious over either of Shichiri I in view of either of Lord II and Cheney and further in view of either Shichiri II or Besson. (See Request at pages 10-14 and 78-79.)

The combined teachings of Shichiri I in view of either of Lord II and Cheney have been discussed in section enumerated “(2)” above.

Examiner incorporates by reference, the locations in Shichiri II and Besson, as cited in the Request, wherein the features of the above claims can be found.

Shichiri II and Besson each teach calibration of the sensors, which is suggestive of a calibration unit. Considered with the features disclosed in Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, Shichiri I considered with either of Shichiri II and Besson raises a substantial new question of patentability as to claim 45 of the ‘752 patent.

Conclusion

So long as a substantial new question of patentability has been raised with respect to at least one claim, all claims are subject to reexamination. Accordingly, **all claims 1-94 are subject to reexamination.**

Application/Control Number: 90/007,910

Page 9

Art Unit: 3992

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in reexamination proceedings are provided for in 37 CFR 1.550(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner of the third party requester must be served on the other party (or parties where two or more third-party-requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. US 6,175,752 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

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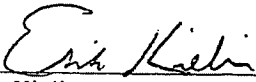
Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

Application/Control Number: 90/007,910

Page 10

Art Unit: 3992



Erik Kielin

Primary Examiner

Central Reexam Unit 3992

(571) 272-1693

March 22, 2006

Conferees:

uRenhar SPRE - CRU - 3992

